



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 10/666,168  
Filing Date: September 19, 2003  
Applicant: Phillip Martin Gibbs et al.  
Group Art Unit: 3738  
Examiner: Bruce E. Snow  
Title: MODULAR PROSTHETIC HEAD HAVING A FLAT  
PORTION TO BE IMPLANTED INTO A CONSTRAINED  
LINER  
Attorney Docket: 5490-000301

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Director of the United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. § 1.131**

Sir:

We hereby declare under penalty of perjury as follows:

1. We are the inventors of the claimed subject matter of the subject patent application.
2. Exhibit A is a page from an engineering notebook that is dated and witnessed, with dates redacted, prior to January 3, 2002.
3. Before January 3, 2002, we conceived of and/or reduced to practice in the United States, a prosthesis system for implantation into an anatomy that includes a ball portion and a cup portion with an entrance. The ball portion has a portion with a dimension equal to or less than a dimension of the entrance to the cup portion. The ball

portion also has a portion with a dimension greater than a dimension of a concave area, as evidence by the following.

4. The page in Exhibit A is entitled "Constrained Liner Idea" that illustrates, in the upper left-hand corner thereof, a liner with a ring that would interact with the liner and it is stated in Exhibit A a "liner that fits ordinary shells with ring that is installed at Biomet".

5. The page in Exhibit A also states that "the endo type head would have a small flat around the equator to allow it to go into the liner. The flat could be positioned in a way that the head would be unlikely to dislocate, but in a position that would allow a surgeon to position the leg to reduce the hip in surgery". This concept is further illustrated in the lower right-hand corner of the page as an exemplary head illustrated with a flat portion thereon.

6. Exhibit B is a R&D Work Request, with date information redacted that is evidence that parts were made by us or on our orders and delivered to us on or before January 3, 2002.

7. Exhibit B includes drawing prints showing configurations and dimensions of various head portions for a femoral head replacement that includes a reduced radius or "flat" portion.

8. Exhibit C is an "Investigational" router, with date information redacted, that illustrates a design of a liner that can include a ring positioned near an opening into an interior portion of the liner. Exhibit C includes a redacted start date before January 3, 2002 (on the first page) and a completion date of January 3, 2002 (shown as the date of "Inspect" on the last page of the "Investigation").

9. The liner illustrated in Exhibit C would allow, and was made for, insertion of a head portion, as illustrated in Exhibit B, to enter the interior portion of the liner when an axis of a the reduced radius area is aligned with an axis of the entrance.

10. Exhibit D is an Applied Technology Mechanical Test Request Form and accompanying drawings and test data, with proprietary data redacted. Exhibit D includes a Requested by W. J. Slone and a Date Submitted of January 3, 2002 and a Test Close-Out Information that illustrates that the requested tests were Conducted by K. Howard and Dated Completed was January 7, 2002.

11. Exhibit D includes a cover sheet that describes that two sets of liners, one with a Cobalt reinforcement ring and one with a titanium reinforcement ring were used with three different types of femoral heads in a lever-out test. The three heads were a 36mm full spherical, a 36mm full spherical with a 34.5 mm circumferential flat, and a 36mm full spherical with a 35.0 mm circumferential flat.


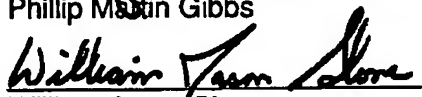
13. Exhibit D also illustrates that the various samples, Sample 4, Sample 5, Sample 12, Sample 13, Sample 6, Sample 7, Sample 14, and Sample 15, that clearly include the circumferential flats in a starting position and In a maximum load position relative to a liner that includes a constraining ring.

14. Exhibit A, with dates redacted illustrates a conception and/or reduction to practice of the subject matter of the claims in the subject application. Exhibits B and C provide evidence that the subject matter of the claims in the present application was reduced to practice and built on or before January 3, 2002. Finally, Exhibit D is evidence that parts embodying the subject matter of the claims of the present invention were tested on or before January 7, 2002

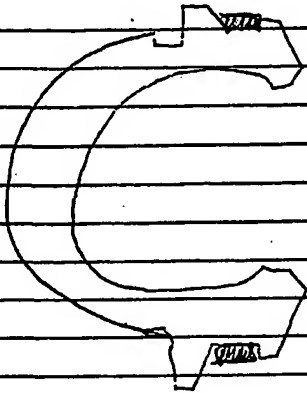
15. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are being made with the knowledge that willful false statements and the like so made are punishable by fine or Imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 3-28-06

Dated: 3-28-2006

  
Phillip Martin Gibbs  
  
William Jason Stone

## CONSTRAINED LINER IDEA



LINER THAT FITS ORDINARY  
SHELLS WITH RING THAT  
IS INSTALLED AT 60 MET

(NO SLITS)

LIKE JASON SLOWE'S  
IDEA. ~~SHRINK THE CUP BY~~

MIGHT EVEN BE ABLE TO  
SHRINK POLY IN COLD ENVIRONMENT / WARM RING  
TO ~~INSTALL~~ ASSEMBLE  
AND/OR

SURGEON INSTALLS THIS LINER IN CUP

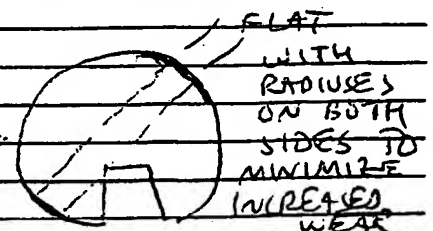
WOULD HAVE LARGE ENOUGH I.D. TO

OFFER GOOD RANGE OF MOTION WITH TYPE  
ONE TAPER.

OFFER VARIOUS NECK LENGTH ENDO TYPE  
HEADS TO MATE WITH I.D. OF LINER

THE REALLY UNIQUE THING HERE IS THAT  
THE ENDO TYPE HEAD WOULD HAVE A SMALL  
FLAT AROUND THE EQUATOR TO ALLOW IT TO  
GO INTO THE LINER. THE FLAT COULD BE  
POSITIONED IN A WAY THAT THE HEAD WOULD  
BE UNLIKELY TO DISLOCATE, ~~IN OTHER WORDS~~  
~~IT WOULD BE IMPOSSIBLE TO~~ BUT IN A POSITION  
THAT WOULD ALLOW THE SURGEON TO POSITION THE  
LEG TO REDUCE THE HIP IN SURGERY

NOTE FULL SPHERE  
AS MUCH AS POSSIBLE  
NO FLAT ☒ YES ☐ NO



SIGNATURE \_\_\_\_\_

READ AND UNDERSTOOD *William V. Stone*

DATE \_\_\_\_\_

DATE \_\_\_\_\_

20

20



## R&D WORK REQUEST

Request Date: [REDACTED]

Engineer: Phil Gibbs  
Project Number:

ext. 1690

Product Name: modular heads with flats

Make Per:

☒ Print (Attached)  
☐ CAD Data File

18399i.tif 18399b.tif 18399c.tif  
18399d.tif 18399e.tif 18399f.tif  
18399g.tif 18399h.tif 18399i.tif  
18399j.tif 18399k.tif 18399a.tif

Using:

Qty: 6

☒ Material On-Hand  
☐ Material Provided  
☐ Parts Provided

Bill To:

☐ Distributor  
☒ Departmental Charge

Price Quoted

Time and Materials:

## Instructions:

this research was originated to support constrained liner development. by decreasing ROM slightly, we should be able to experience much greater pull-out and lever-out and still be able to assemble. question is increased wear concerns

Shop Log					
Date	Hrs	Name	Notes From Shop		
[REDACTED]	6.00	Monty Lackey			
[REDACTED]	10.00	Don DeCook			
[REDACTED]	8.00	Monty Lackey			
[REDACTED]	8.00	Monty Lackey			
			Traceable Material		
			Material	Lot #	Location

Vendor No:

Engineering Information

P.O. No:

Req, No:

Comp. Date:

Completed Documents:

Department:	Hips	Other:
Classification:	R&D	
Total Hours:	32.00	
Order No.: 18399		

**△ SPHERICITY TOLERANCE: 5.0002 IN (25 MICRONS).**

**△ MARK: "B", LOT NO. AND "STD" PER BLOMET SPEC. 1.6.**

**△ INTERIOR AND EXTERIOR BACK SURFACE MACHINE SPHERE R: POLISH.**

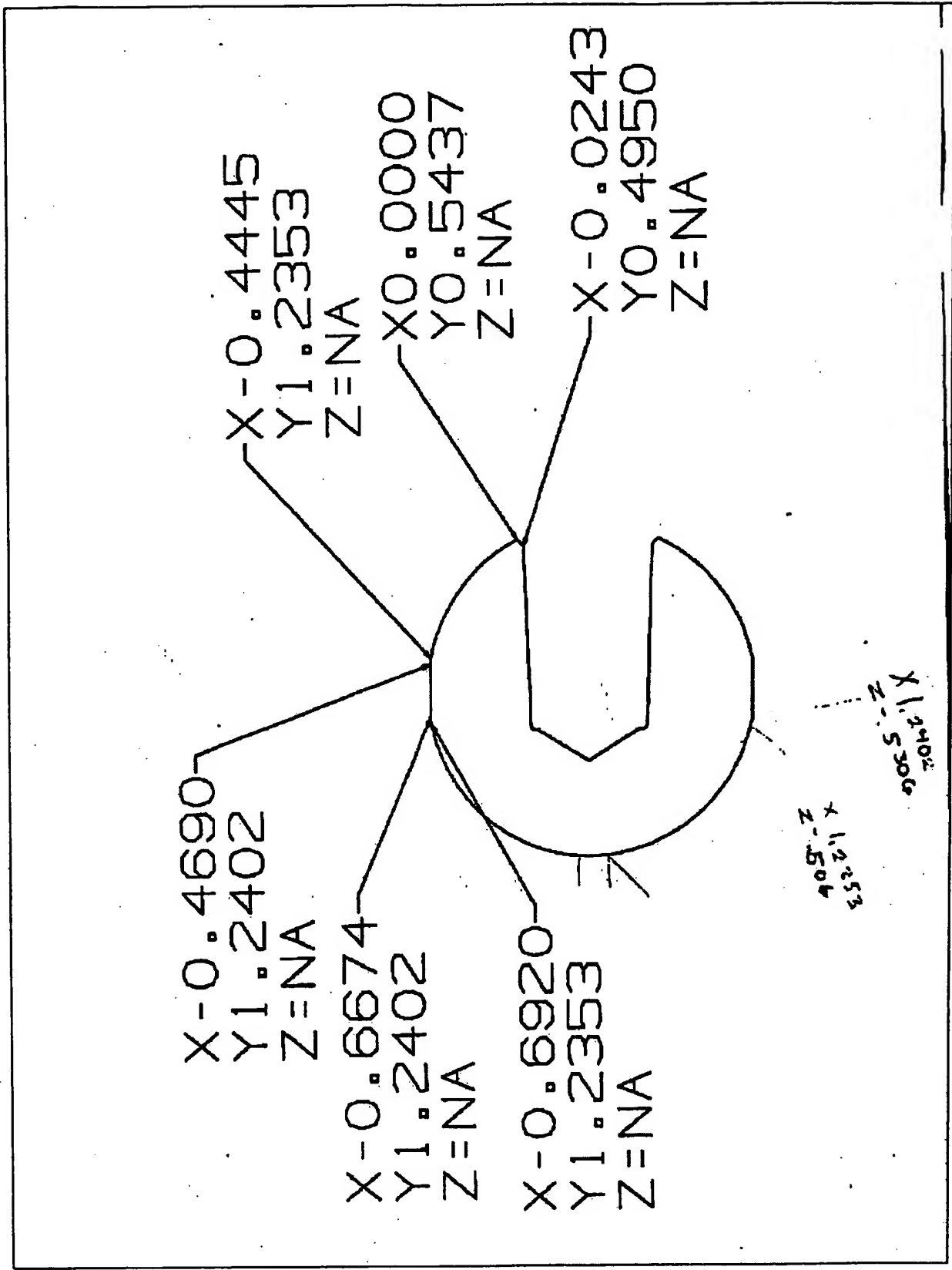
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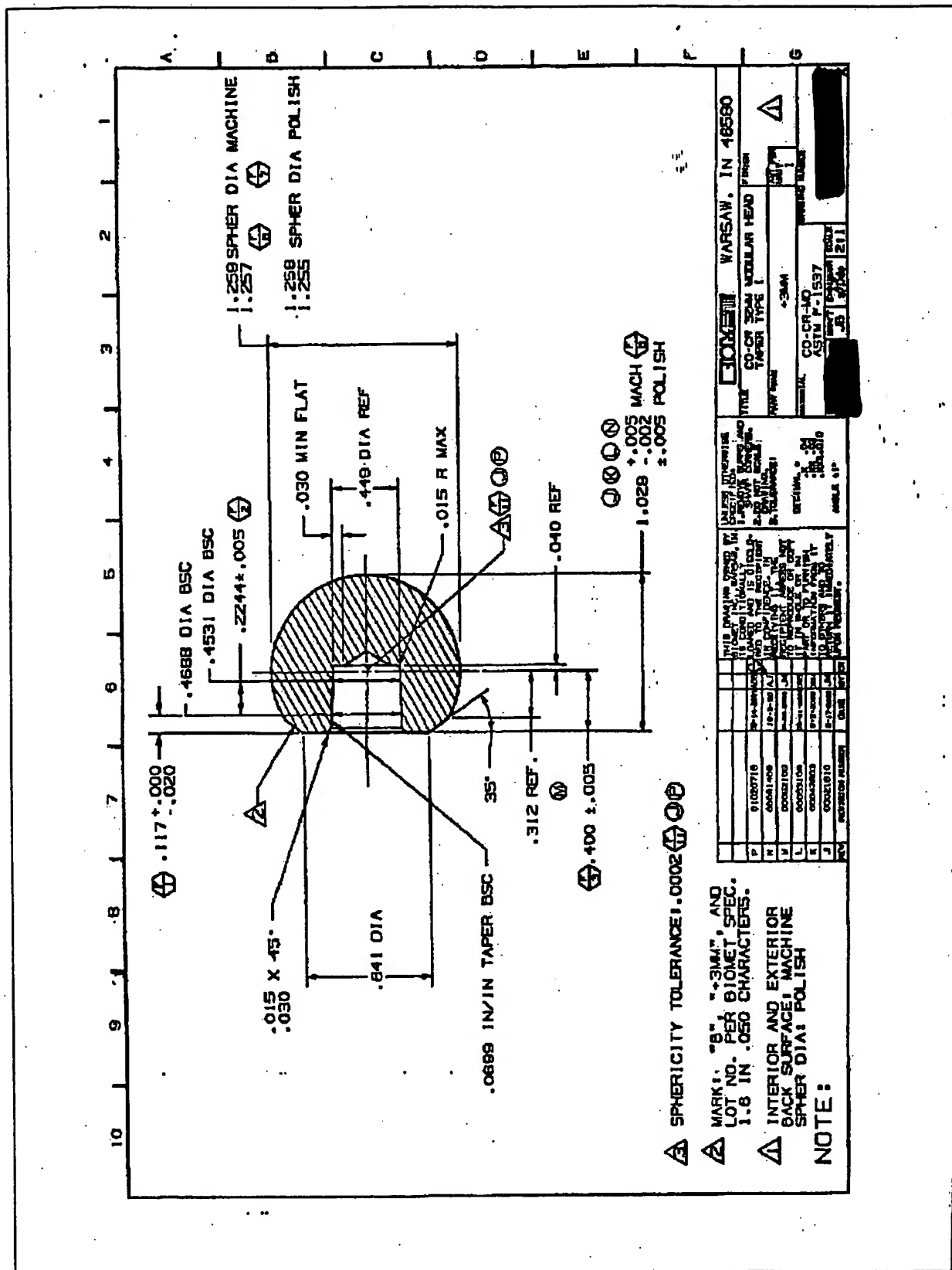
moduff\RG\bbbs\ HEADS W-F\lats\ 32mm Std Head w\31Bmm Flat.prnt F

TOLERANCE: 5.0002 IN (25 MICRONS)		TOLERANCE: 5.0002 IN (25 MICRONS)	
MARK: "B", LOT NO. AND "STD" PER BLOMET SPEC. 1.6.		MARK: "B", LOT NO. AND "STD" PER BLOMET SPEC. 1.6.	
INTERIOR AND EXTERIOR BACK SURFACE MACHINE SPHERE R: POLISH.		INTERIOR AND EXTERIOR BACK SURFACE MACHINE SPHERE R: POLISH.	
NOTE:		NOTE:	

moduff\RG\bbbs\ HEADS W-F\lats\ 32mm Std Head w\31Bmm Flat.prnt F







PAGE: 49

TIME: 21:11

DATE: [REDACTED]

C A R L Z E I S S Measurement system

No. TASK	REM BY	ACTUAL	NOMINAL	UPPERTOL	LOWERTOL	DEVIATION	OVER
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4. VALID: EDWARDS SPHERE ILLUMINATION

1 SPHERE	Z	.57883					
	R	.77302					
	ED	.00173					

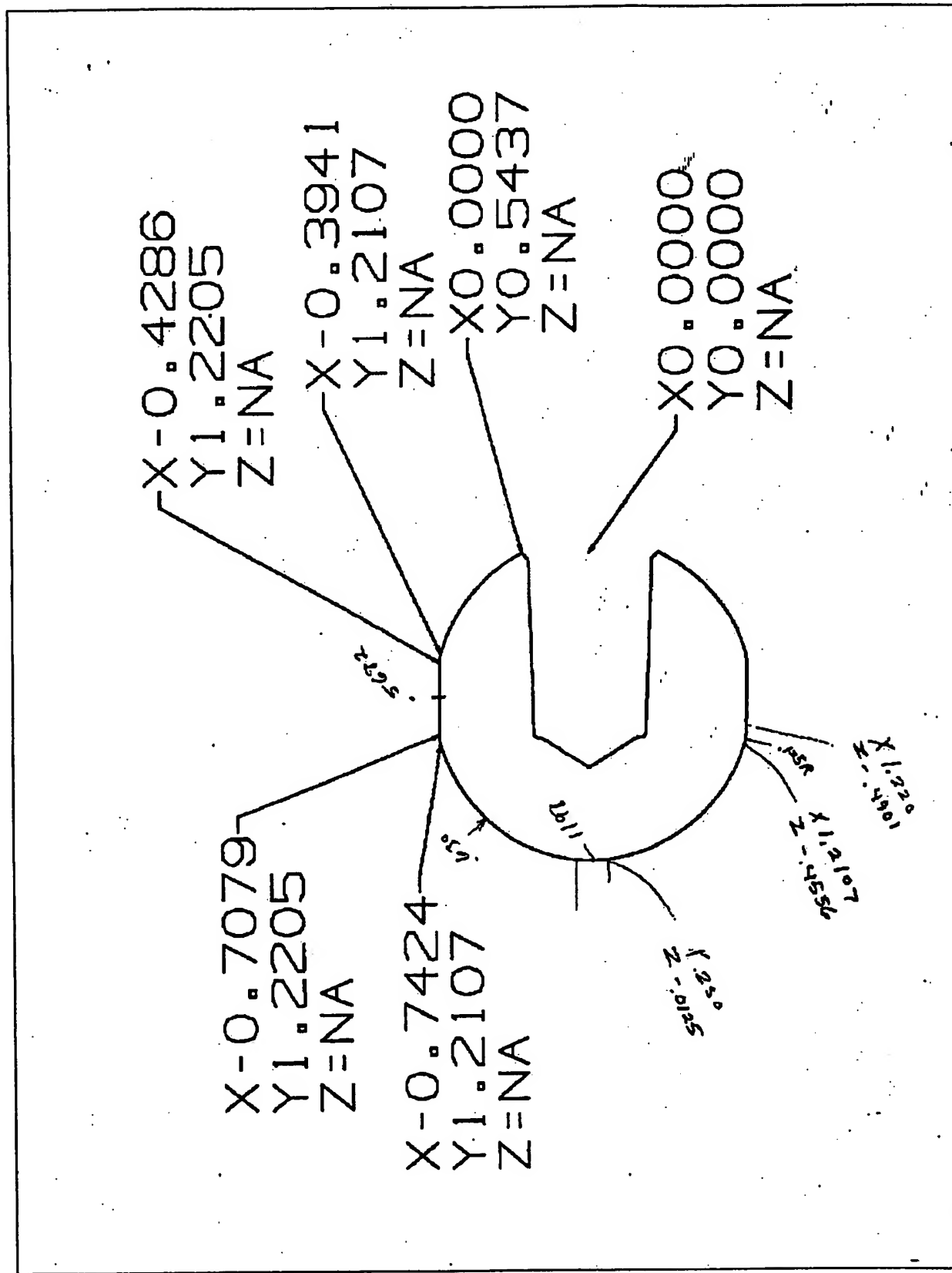
PAGE: 03

TIME: 0:14

DATE: [REDACTED]

**C A K L    Z E I S S    Measurement system**


No.	TASK	KEM	SY	ACTUAL	NOMINAL	UPPER TOL	LOWER TOL	DEVIATION	OVER
Z VALUE EQUALS SPHERE LOCATION									
1	SPHERE		Z	.60395					
			R	.71043					
			Rd	.00029					



mdur\m\pg\bb\HEADS w-Flats\32mm Std Head w31mm Flat.prnt

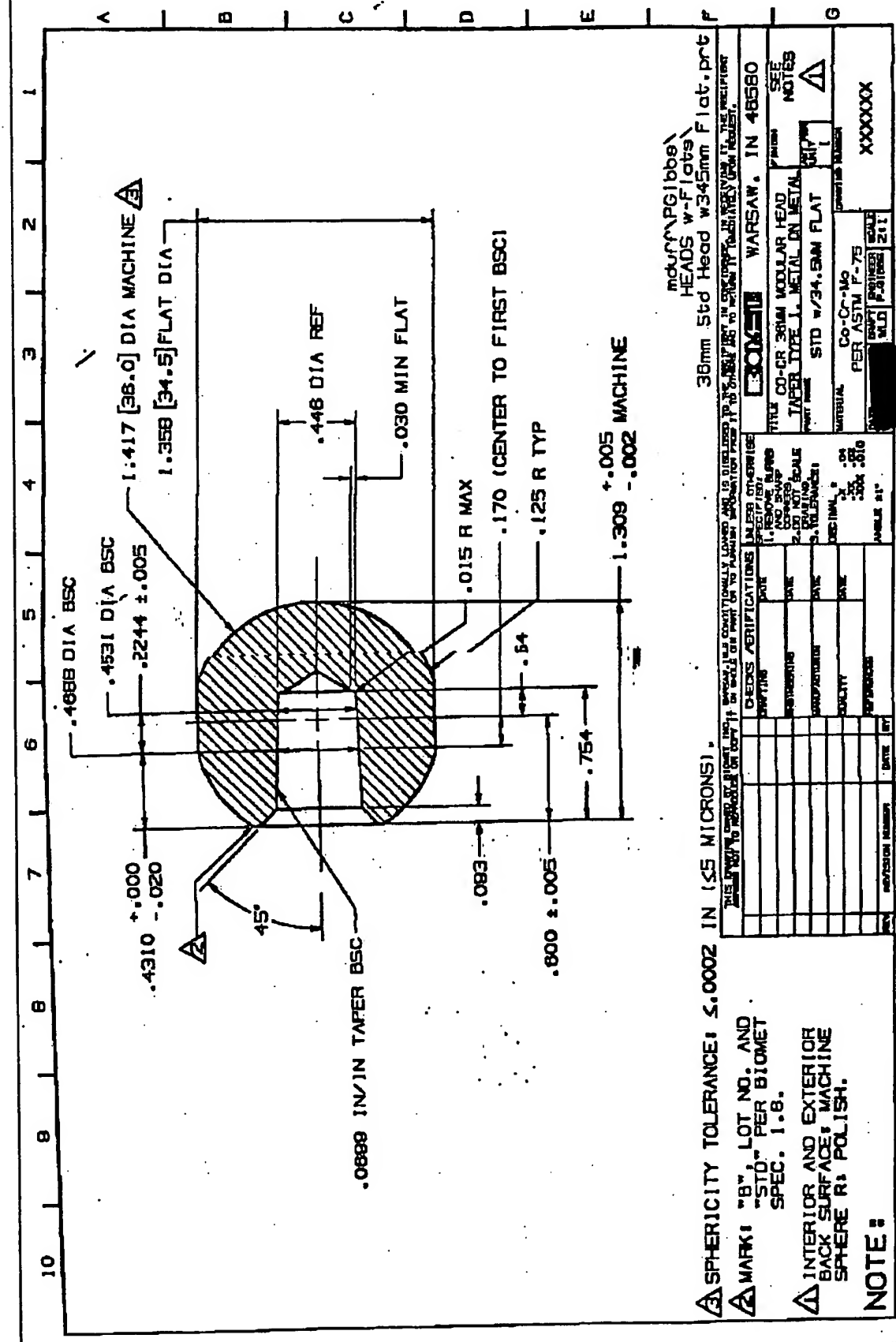
TO THE NEEDS OF THE CONSUMERS IN PROVIDING IT THE RECIPIENTS  
AT THE SAME TIME TO MEET THE NEEDS OF THE RECIPIENTS

**WARSAW. IN 46580**

TITLE CO-OR 32MM MODULAR HEAD TAPER TYPE 1. METAL ON METAL FINISH STD W/31MM FLAT	WARSAW. IN 46580 SEE NOTED 
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Co-Dr-Mo	XXXXXX
PER ASTM F-75	

[illegible]



indur\PGibbs\HEADS w-Flats\36mm Std Head w345mm Flat.prt

TITLE		CO-OP 36MM MODULAR HEAD		FINISH	SEE NOTES
PART NAME		STD w/34.5MM FLAT		SHIP	Δ
MATERIAL		CO-OP-40		QUANTITY	XXXXXX
PER ASTM F-75		HOLD		DATE	2/11



3) SPHERICITY TOLERANCE:  $\pm 0.002$  IN (5 MICRONS).

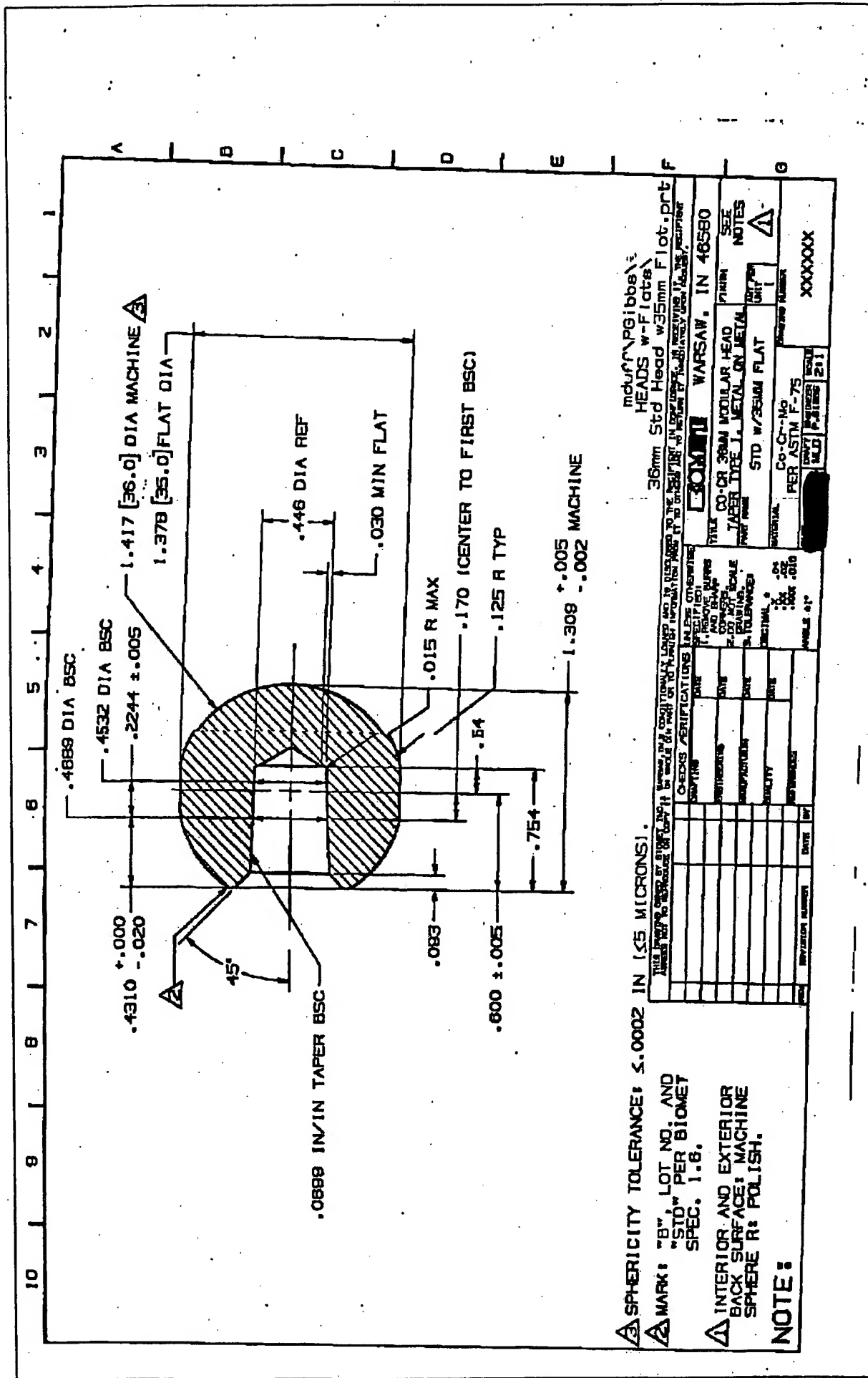
**△ MARK:** "B", LOT NO. AND  
"STD" PER BIOMET  
SPEC. 1.B.

**△ INTERIOR AND EXTERIOR  
BACK SURFACE: MACHINE  
SPHERE R: POLISH.**

## NOTE

CO-OR 38MM MODULAR HEAD		FURNISH		SEE	
INFER TYPE L METAL ON METAL				NOTES	
PART NAME		STANDARD			
STD W/O FLAT					
MATERIAL		CO-CR-MO		G	
PER ASTM F-75					
DRAWN BY		CHECKED BY		X00000X	
DATE		DATE			
PAGES		PAGES			
211		211			

[illegible]





## R&D WORK REQUEST

Request Date: [REDACTED]

Engineer: Phil Gibbs  
Project Number:

ext. 1690

Product Name: modular heads with flats

Make Pen

- ☒ Plans (Attached)  
☐ CAD Data File

Using

- ☒ Material On Hand  
☐ Material Provided  
☐ Parts Provided

Qty: 6

Bill To: ☐ Distributor  
☒ Departmental Charge  
Price Quoted

NEEDS ASAP  
Time and Materials:

### Instructions:

this research was originated to support constrained liner development. by decreasing ROM slightly, we should be able to experience much greater pull-out and lever-out and still be able to assemble. question is increased wear concerns

Shop Log				
Date	Hr's	Name	Notes From Shop	
	6	Monty		
	10	Dulok		
	8	Monty		
	8	Monty		
			Traceable Materials	
		Material	Lot#	Location
		01-02-0014A	990932	the cage

Vendor No:

P.O. No:

Req. No:

Comp. Date: Complete

Completed Documents:

Engineering Information		
Department:	Hr's	Other:
Classification:		
Total Hours:	0.00	
Order No.:	18399	

ENTERED

**ATTACH SAMPLE LABEL HERE:**



**LOT 815390**



**LOT** 815390

QTY. 1

**BOMET ORTHOPEDICS, INC.**  
68 EAST FIELD DRIVE  
P.O. BOX 687  
WARSAW, IN 46581 USA

STERILE  
2002-01

COMPONENT	ITEM	DESCRIPTION	U/M	TYPE	QTY.	RECD	OPER
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	755830	029212/11		+54
	728000	029212/18		+27
	728000	033212/19		27
	788110	029212/20		+18 1/2
			05093438	+18 1/2
			TOOL	PROCESS

WORK CENTER	OF.	188175	TOOL	PROCESS	1136	LABEL
	SEQ.	OPERATION DESCRIPTION	NUMBER	NUMBER		COLOR

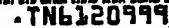
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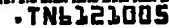
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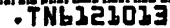
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28000	0060	MILL SCALLOPS	VR0207	5.00
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28010 0080 BORE I.D. *LB4603* 5.00

[illegible]

**MM**

**CURRENT DATE:**

**PAGE: 3**

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**20.000 88**

## PCS, PRR TOOL PROCESS

**LABEL**

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[illegible]

**.TN6121021**

**DATE** \_\_\_\_\_

**CLOCK  
NUMBER**

OPER.  
NUMBER

PIECES  
PROD.

**SCRAP  
PIECES**

**ACC**

**INSPECT  
REJ**

9/1

**CLOCK  
NUMBER**

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100. [REDACTED]

**.TN6121039**

**1**

DATE \_\_\_\_\_

**CLOCK  
NUMBER**

OPER.  
NUMBER

PIECES  
PROB

SCRAP  
PIECES

ACC

**INSPECT**  
**RELJ**

8/1

**CLOCK  
NUMBER**

## REWORK PIECES

**33.33**

[illegible]

• TN6323047

DATE/

**CLOCK  
NUMBER**

OPER.  
NUMBER

PIECE  
PROD.

SCRAP  
PIECES

ACCO

INSPECT  
REJ

8/8

CLOCK  
NUMBER

## REWORK PIECES

"Rush"  
SHIP SECURE FU.  
1-4-02

TV  
Tanner)

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12116 0180 PACKAGE STERILE

**33.33**

• TN6121062

12118 0200 LABEL & BOX

**30.03**

LOGO

SEE TIMMY RHODES  
TSL 1-9-02

-TN6121070

1 RETURN TO GREGG PORTER BXT 1852

[illegible]

**MR.**

PAGE: ' 5 . ,

WORK CENTER	OP. SEQ.	OPERATION DESCRIPTION	PCS. HOUR	PER TOOL NUMBER	PROCESS NUMBER	LABEL COLOR
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**83.33**



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[illegible]

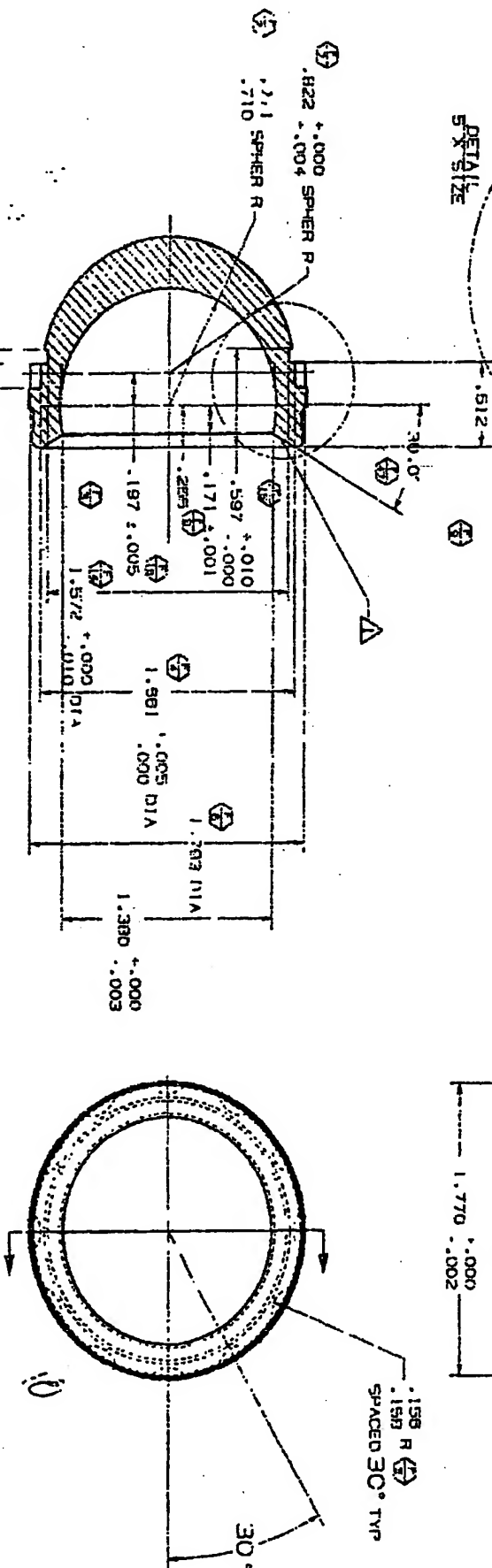
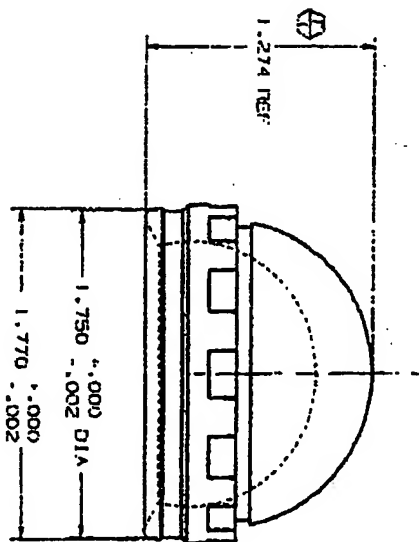
09000 0240 STERILIZE



-TN6121096

[illegible]





MARK, "B" LOT NO., AND "PROTOTYPE" (SIZE),  
TERMINOLOGY SPEC. 1.61.  
EXAMPLE: B XXXXX "PROTOTYPE"

**NOTE:**

1. NAME OF THE PARTY OR PERSON 2. ADDRESS 3. CITY 4. STATE 5. ZIP CODE 6. COUNTRY 7. PHONE NUMBER 8. FAX NUMBER 9. TELETYPE 10. TELEFAX 11. TELEVISION 12. RADIO 13. OTHER		14. DATE OF BIRTH 15. SEX 16. RACE 17. HEIGHT 18. WEIGHT 19. HAIR 20. EYES 21. SKIN 22. BLOOD TYPE 23. FINGERPRINTS 24. SIGNATURE 25. PHOTOGRAPH 26. OTHER		27. DATE OF DEATH 28. CAUSE OF DEATH 29. MANNER OF DEATH 30. PLACE OF DEATH 31. TIME OF DEATH 32. LOCATION OF DEATH 33. OTHER		34. DATE OF INTERVIEW 35. INTERVIEWER 36. WITNESS 37. DATE OF REPORT 38. REPORTER 39. REVIEWER 40. APPROVER 41. OTHER		42. DATE OF REVIEW 43. REVIEWER 44. WITNESS 45. DATE OF REPORT 46. REPORTER 47. REVIEWER 48. APPROVER 49. OTHER		50. DATE OF REVIEW 51. REVIEWER 52. WITNESS 53. DATE OF REPORT 54. REPORTER 55. REVIEWER 56. APPROVER 57. OTHER		58. DATE OF REVIEW 59. REVIEWER 60. WITNESS 61. DATE OF REPORT 62. REPORTER 63. REVIEWER 64. APPROVER 65. OTHER		66. DATE OF REVIEW 67. REVIEWER 68. WITNESS 69. DATE OF REPORT 70. REPORTER 71. 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REVIEWER 140. WITNESS 141. DATE OF REPORT 142. REPORTER 143. REVIEWER 144. APPROVER 145. OTHER		146. DATE OF REVIEW 147. REVIEWER 148. WITNESS 149. DATE OF REPORT 150. REPORTER 151. REVIEWER 152. APPROVER 153. OTHER		154. DATE OF REVIEW 155. REVIEWER 156. WITNESS 157. DATE OF REPORT 158. REPORTER 159. REVIEWER 160. APPROVER 161. OTHER		162. DATE OF REVIEW 163. REVIEWER 164. WITNESS 165. DATE OF REPORT 166. REPORTER 167. REVIEWER 168. APPROVER 169. OTHER		170. DATE OF REVIEW 171. REVIEWER 172. WITNESS 173. DATE OF REPORT 174. REPORTER 175. REVIEWER 176. APPROVER 177. OTHER		178. DATE OF REVIEW 179. REVIEWER 180. WITNESS 181. DATE OF REPORT 182. REPORTER 183. REVIEWER 184. APPROVER 185. OTHER		186. DATE OF REVIEW 187. REVIEWER 188. WITNESS 189. DATE OF REPORT 190. REPORTER 191. REVIEWER 192. APPROVER 193. OTHER		194. DATE OF REVIEW 195. REVIEWER 196. WITNESS 197. DATE OF REPORT 198. REPORTER 199. REVIEWER 200. APPROVER 201. OTHER		202. DATE OF REVIEW 203. REVIEWER 204. WITNESS 205. 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**Applied Technology Mechanical Test Request Form**

Project : Constrained Liner II

Project #: HP000180

Title: Lever-out with 3 different 36mm Co-Cr Modular Heads

Test Type: ☐ Fatigue ☒ Static ☐ Rotating Beam ☐ Wear  
☐ Other (specify) \_\_\_\_\_

Conducted: ☒ In-House  
☐ Outside Lab (specify) \_\_\_\_\_

Test Components: (Part A is primary component for test)

	Part Name	Part #	Lot #	Size	Qty
A	23 Constrained +5 Liner w/Cobalt Ring	Investigational	815390	23	6
B	23 Constrained +5 Liner w/Cobalt Ring	Investigational	815390	23	6
C	36mm Fully-spherical Modular Head	Investigational		36mm	1
D	36/34.5mm Fully-spherical Modular Head with 34.5mm circumfrenclal flat	Investigational		36mm	1
E	36/35.0mm Fully-spherical Modular Head with 35.0mm flat	Investigational		36mm	1

If the test components are not finished production parts, please state why.

Material:      A B C D E                      A B C D E  
                     X      Ti-6Al-4V                      Stainless Steel (type) \_\_\_\_\_  
                     .X    X X X CoCr                      X X      UHMWPE  
    P85/15                      LactoSorb  
    P82/18                      Other (specify) \_\_\_\_\_  
                         Ceramic (specify) \_\_\_\_\_

Processing: (Check all that apply for each test component)

A B C D E	A B C D E	A B C D E
X X X Wrought	Forged	Cast
Molded	X X X X X Machined	X X X X X Passivated
Welded	Heat Treated (specify)	X X      Packaged
Shot Peened Intensity	Blasted (# _____)	HA Coated
Ion Implanted	X X      Ceramic Bead Blast	Full Plasma Spray
TiN Coated	X X X Laser Etched	MacroBond P Spray
Chem Etched	X X      Sterilized (gamma)	Plasma Nitrided
Finished Goods (Lot#) X X X X X	Cleaned (powerwash/alcohol)	Other _____
Wire EDM'D	X X X Honed	X X X Polished

Specify differences between multiple specimens: The only difference between the two liners is the constraining ring. The liners themselves are from the same lot.

Objective(s) of Test: Determine the amount of torque required to lever-out three different 36.0 mm modular head designs from the liner, as well as determining how much if any a Cobalt Reinforcement ring will strengthen design from a Titanium Reinforcement Ring.

Test Procedure # See attached page (Outline the desired procedure if not a standard procedure).

Test Specifications: \_\_\_\_\_

Deviations from Standard: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Data to be Collected: ☒ Load vs. Deflection  
☒ Max. Load  
☐ Weight Loss

☐ # of Cycles to Failure  
☒ Max. Deflection  
☐ Other \_\_\_\_\_

Special Instructions: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Requestor to be present when test is started? ☒ Yes ☐ No

Requested By: W. F. Stone Date Submitted: 1/3/2002

Test Close-Out Information:

Conducted By: K. Howard Date Completed: 1-7-2002

Lab Book Reference: S-24 pg. 23

Test Specimen Disposition: ☒ Archived ☐ Returned To Engineer ☐ Discarded

Requestor Comments:

\_\_\_\_\_

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Blomet Mechanical Test Lab  
Static Test Data Sheet

Test # MT2439 Date Test Started 1-7-2002 Requestor J. SLOVE

Title CONSTRAINED LEMER II; LEMER Out Machine ID RAYMOND

Actuator Rate .008"/SEC. = .40"/MIN.

Sketch of Test Set-Up: (note all relevant distances and angles)

Specimen#	Max Load	DATA FILE:	Specimen#	Max Load	DATA FILE:
sz. 36/34 1/2	FLAT HEAD		sz. 36	FULL HEAD	
#4.	<del>243</del> 41.6 lbs.	2439-1.TXT	#8.	40.5	2439-9.TXT
#5.	43.2	2439-2.TXT	#11.	41.0	2439-10.TXT
#12.	46.6	2439-3.TXT			
#13.	46.4	2439-4.TXT			
sz. 36/35	FLAT HEAD				
#6	43.5	2439-5.TXT			
#7	44.5	2439-6.TXT			
#14	49.3	2439-7.TXT			
#15.	46.0	2439-8.TXT			

Average: \_\_\_\_\_

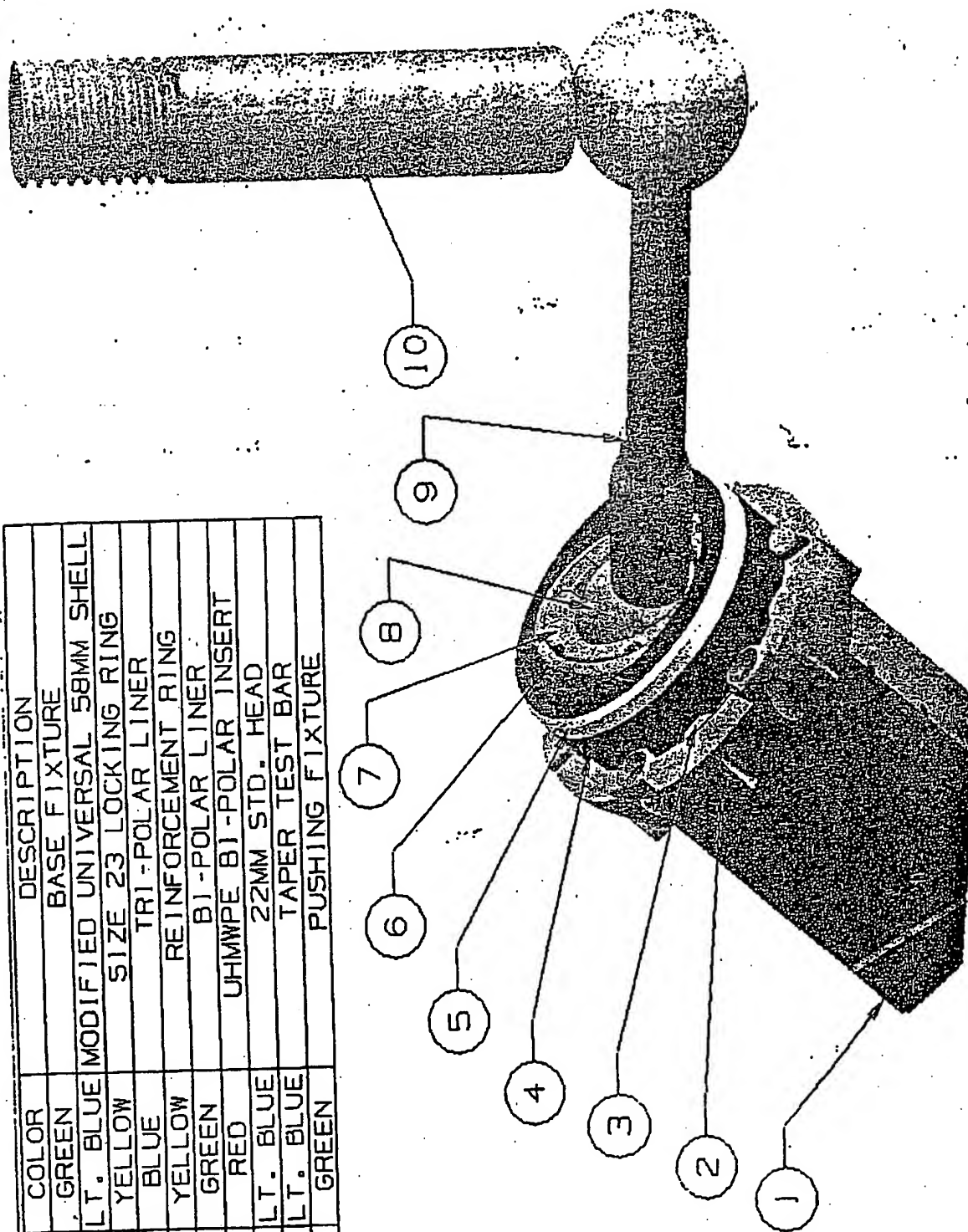
Average: \_\_\_\_\_

Notes: \_\_\_\_\_

Date Test Completed: 1-7-2002 Conducted by: K. HOWARD

Book# S-24 Continued on Page \_\_\_\_\_ Page 23

OBJECT NO.	COLOR	DESCRIPTION
1	GREEN	BASE FIXTURE
2	LT. BLUE	MODIFIED UNIVERSAL 58MM SHELL
3	YELLOW	SIZE 23 LOCKING RING
4	BLUE	TRI-POLAR LINER
5	YELLOW	REINFORCEMENT RING
6	GREEN	B1-POLAR LINER
7	RED	UHMWPE B1-POLAR INSERT
8	LT. BLUE	22MM STD. HEAD
9	LT. BLUE	TAPER TEST BAR
10	GREEN	PUSHING FIXTURE



HEAD Sz. 36/34 1/2 FLAT

LEVER-OUT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587 UPRISAW, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#1. 2439-1

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/34 1/2 FLAT

LEVER-OUT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587 UPRISAW, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#5. 2439-2 43.2 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/34 1/2 FLAT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587 UPRISAW, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#12. 2439-3 46.6 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/34 1/2

LEVER OUT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587 UPRISAW, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#13. 2439-4 46.4 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/35 FLAT

LEVER OUT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587 UPRISAW, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#6. 2439-5 43.5 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587 UPRISAW, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#7. 2439-6 44.5

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/35 FLAT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587 UPRISAW, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#14. 2439-7 49.3 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/35 FLAT

LEVER-OUT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587 UPRISAW, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#15. 2439-8 45.99 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

\* FOOT RUN CAME OUT OF SWEET

HEAD Sz. 36/36

LEVER-OUT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587 UPRISAW, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#8. 2439-9 40.5 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

HEAD Sz. 36/36

LEVER-OUT

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587 UPRISAW, IN 46581 USA

REF. INVESTIGATIONAL

INVESTIGATIONAL

RETURN TO GREG PORTER

#16. 2439-10 41.0 lbs.

LOT 815390

AFFIX TO PATIENT RECORDS

**Test Report MT-2439**  
**Lever-Out with 3 different 36mm Co-Cr Modular Heads**

**Test Site:**

Biomet Inc.  
Airport Industrial Park  
Warsaw, IN 46580

**Conducted By:**

Jason Slone  
Kelly Howard

Development Engineer  
Laboratory Technician/Supervisor

*Jason Slone* 12/11/2002

**Dates Conducted:**

January 7, 2002

**Objective:**

Determine the amount of torque required to lever-out three different 36.0 mm modular head designs from the liner, as well as determining how much if any a Cobalt Reinforcement ring will strengthen design from a Titanium Reinforcement Ring.

**Materials:**

Part Name	Part Number	Lot Number	Size	Quantity
23 Constrained +5 Liner w/Cobalt Ring	Investigational	815390	23	6
23 Constrained +5 Liner w/Ti-6Al-4V Ring	Investigational	815390.	23	6
CoCr Reinforcement Ring	Investigational	R&D	23	6
Ti-6Al-4V Reinforcement Ring	Investigational	R&D	23	6
36mm Full Sphere Modular Head	Investigational	R&D	36	1
36mm/35 flat Full Sphere Modular Head	Investigational	R&D	36/35	1
36mm/34.5 flat Full Sphere Modular Head	Investigational	R&D	36/34.5	1

The 23 Constrained Liners were manufactured complete at Biomet Warsaw. The Retaining Rings and Modular Head were manufactured at Biomet Warsaw in the Research and Development area. The rings were manufactured complete except for chemical etch, sterilization and packaging processes, which have no effect of this test.

**Methods:**

See Attached Sheet for Test Procedure

## Calculations:

### Lever-Arm:

The calculated lever-arm for this test was done using the CAD system. See Attached Figures with Sample Numbers. The constrained liner design was taken and rotated until the lever-out bar was horizontal. Then the head was constrained so that it must pop out of the liner perpendicular to the face of that liner. The maximum displacement was then used to determine where the Force from the actuator was being placed.

### Percent Increase of CoCr Reinforcement Ring:

$$[(\text{Average Torque Ti-6Al-4V}) - (\text{Average Torque CoCr})] / (\text{Average Torque Ti-6Al-4V})$$

## Results:

The results of the lever out test were as follows.

Mechanical Test 2439					
Specimen #	Maximum Displacement (in)	Maximum Recorded Force (lbs)	Calculated Lever Arm (in)	Calculated Torque (in-lbs)	Modular Head Size
4	0.652	41.6	3.216	133.8	36/34.5
5	0.662	43.2	3.215	138.9	
12	0.666	46.5	3.215	149.5	
13	0.719	46.4	3.205	138.9	
6	0.687	43.5	3.213	139.8	36/35.0
7	0.746	44.5	3.206	142.7	
11	0.690	49.8	3.213	158.4	
15	0.680	46.9	3.215	147.8	
8	0.720	40.5	3.209	130.0	36/36
16	0.693	42.9	3.211	121.7	

Note: Blocks in Gray are Liners with a Cobalt Chrome Reinforcement Ring;  
Bold Numbers are maximum Torque

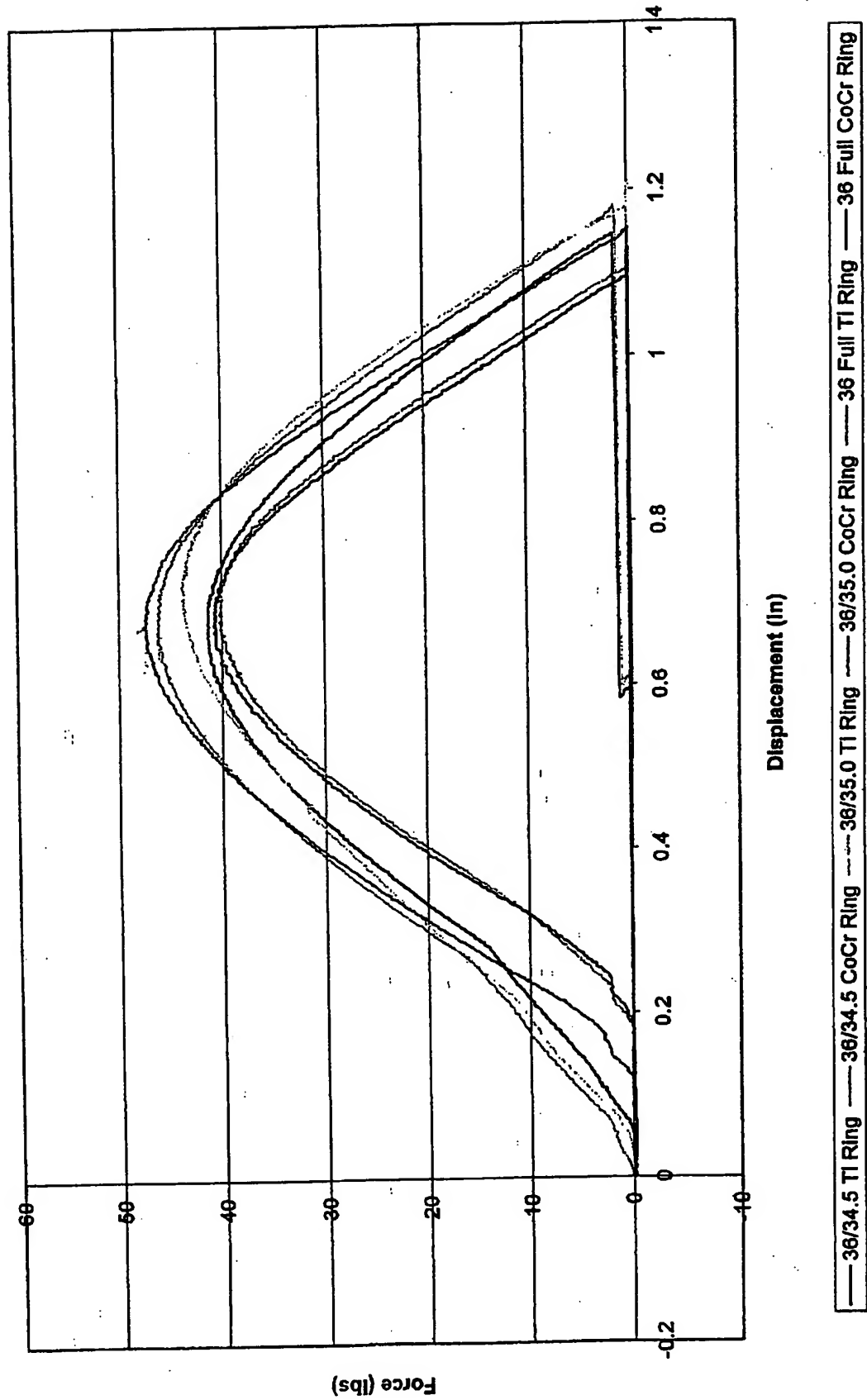


**Conclusion:**

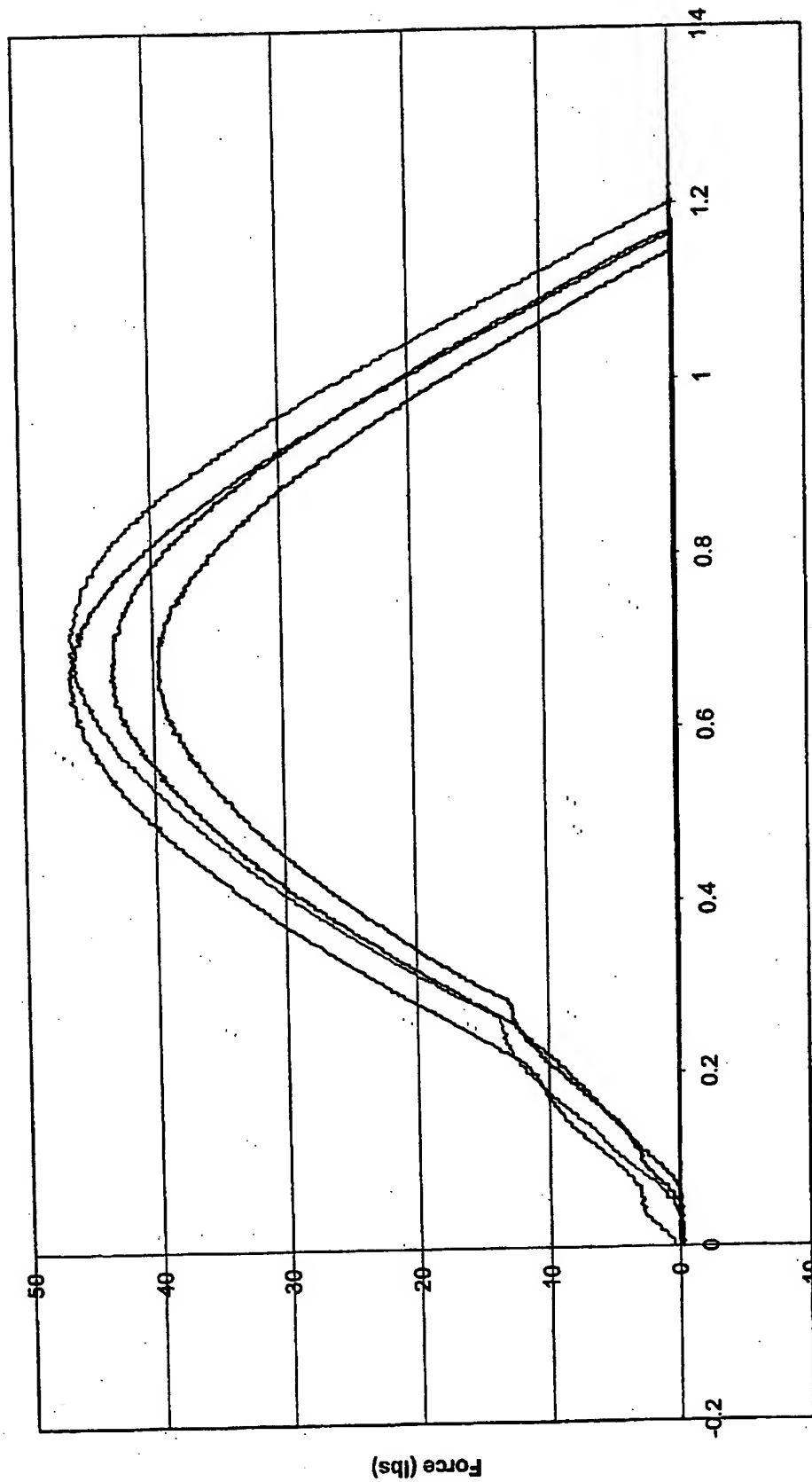
As can be seen from the data the maximum amount of torque is acquired using a CoCr Reinforcement Ring with a 36/35.0 modular head. This scenario makes sense because it will displace a small amount of polyethylene when placed into the liner, but maintain the most amount of surface area when in a lever-out position. See tests reports MT2239 and MT2412 showing what the difference can be when using a full spherical head compared to a head that is not a complete sphere.

The 36/35.0 modular head shows the best results with either the CoCr or Ti-6Al-4V Reinforcement Rings. The CoCr Reinforcement Ring increases the leverout strength of this UHMWPE constrained liner design by roughly 9%.

Average Force vs. Displacement

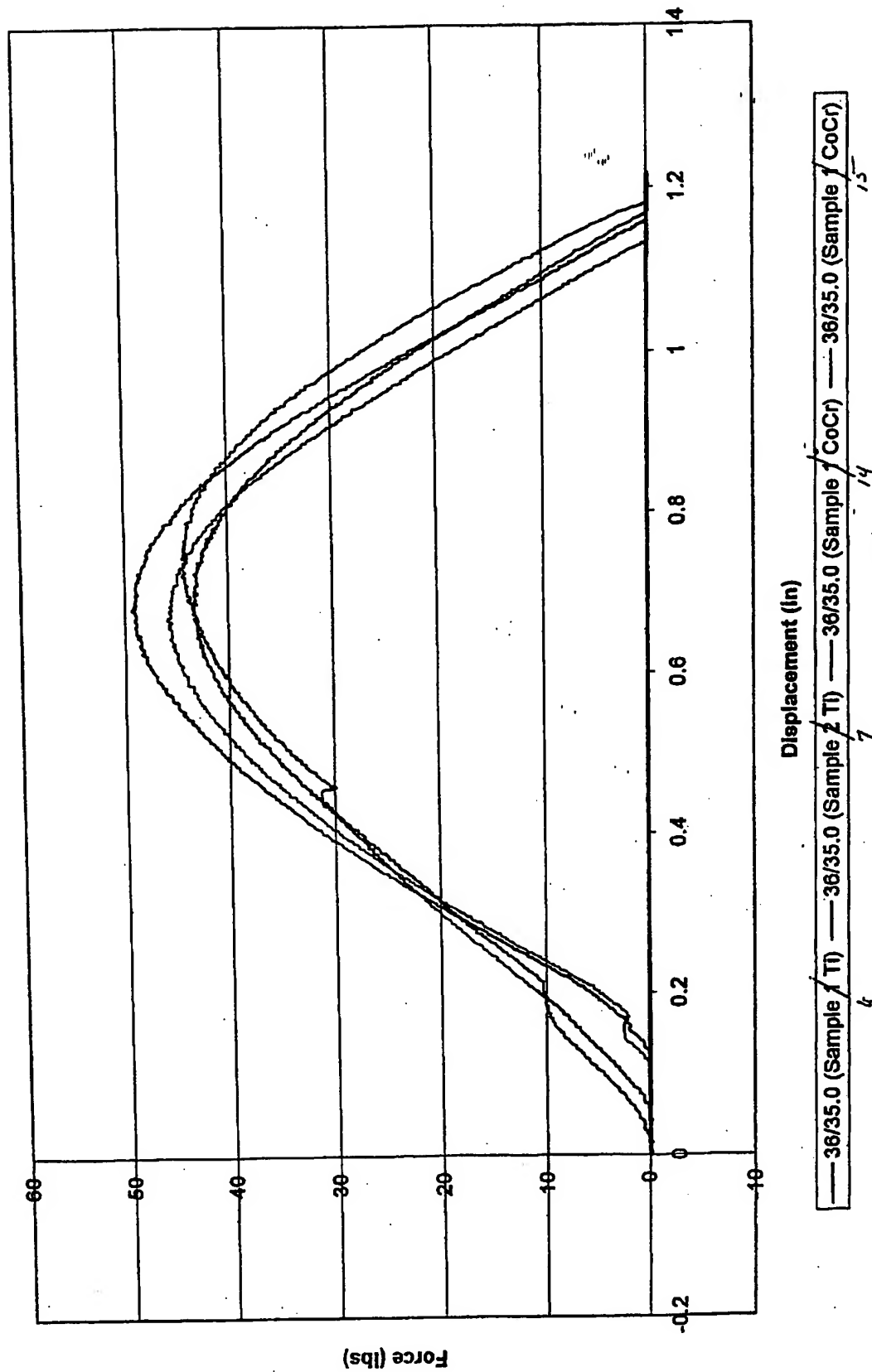


Force vs. Displacement

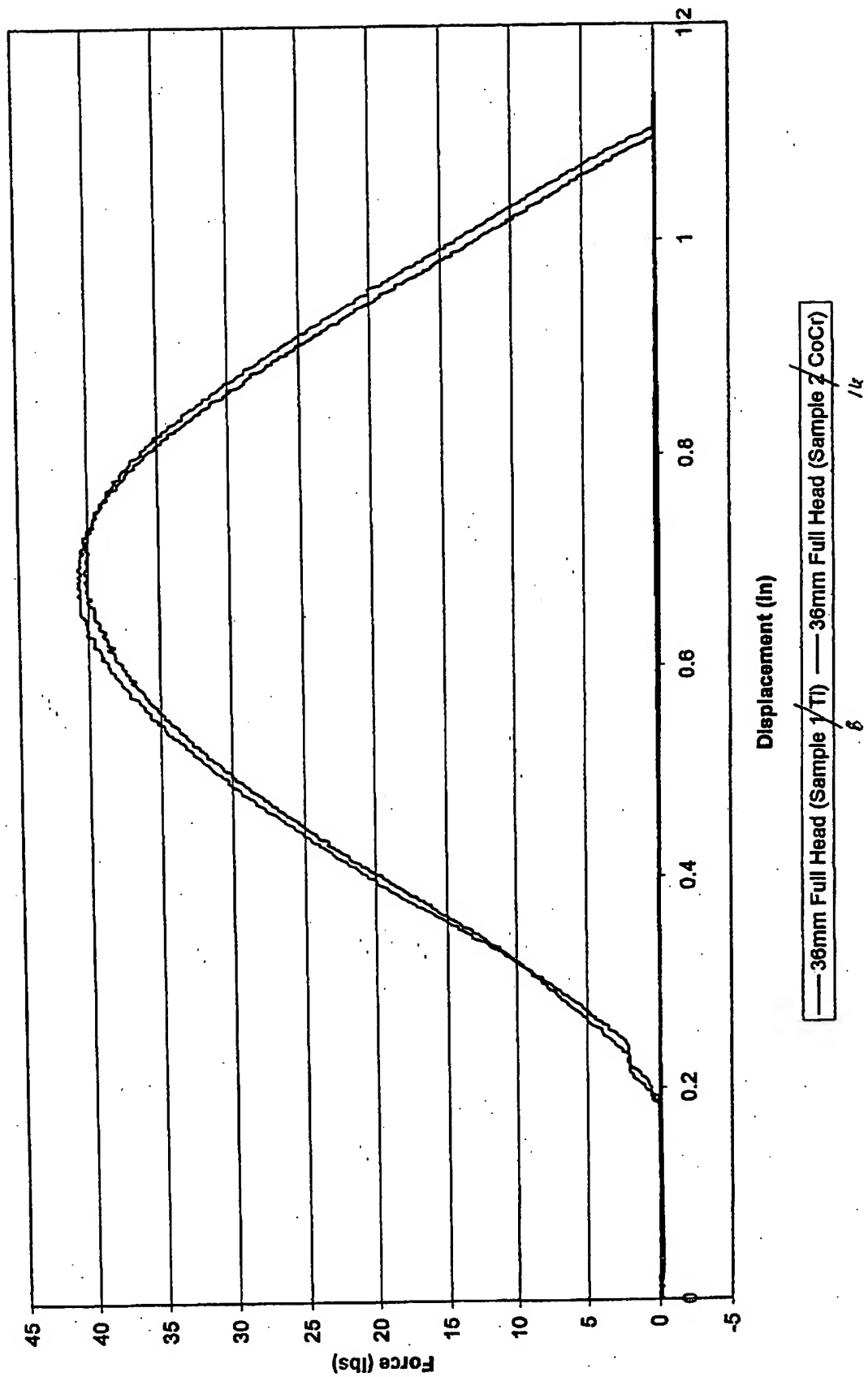


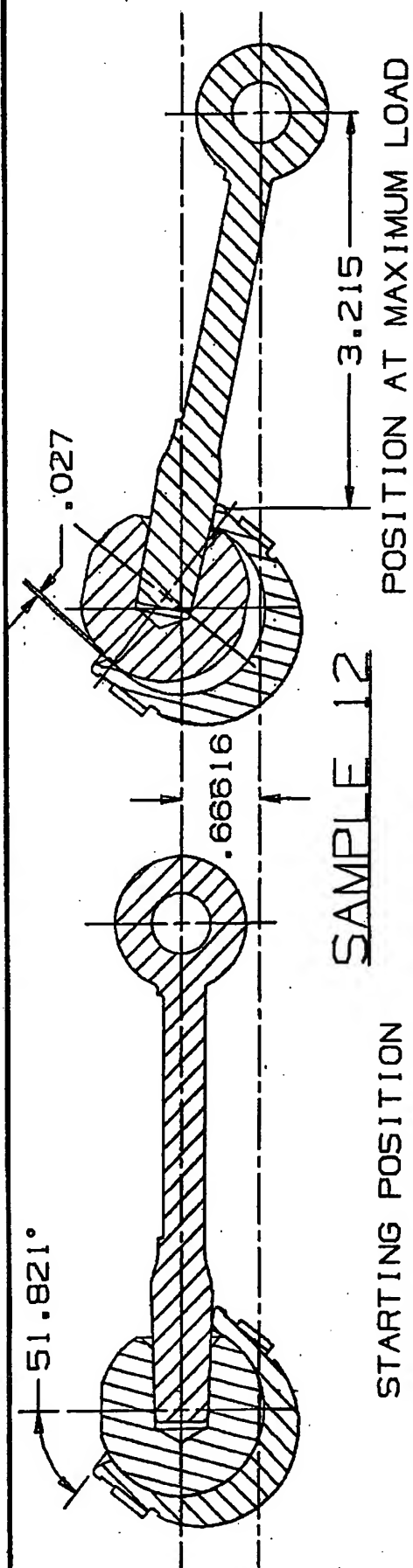
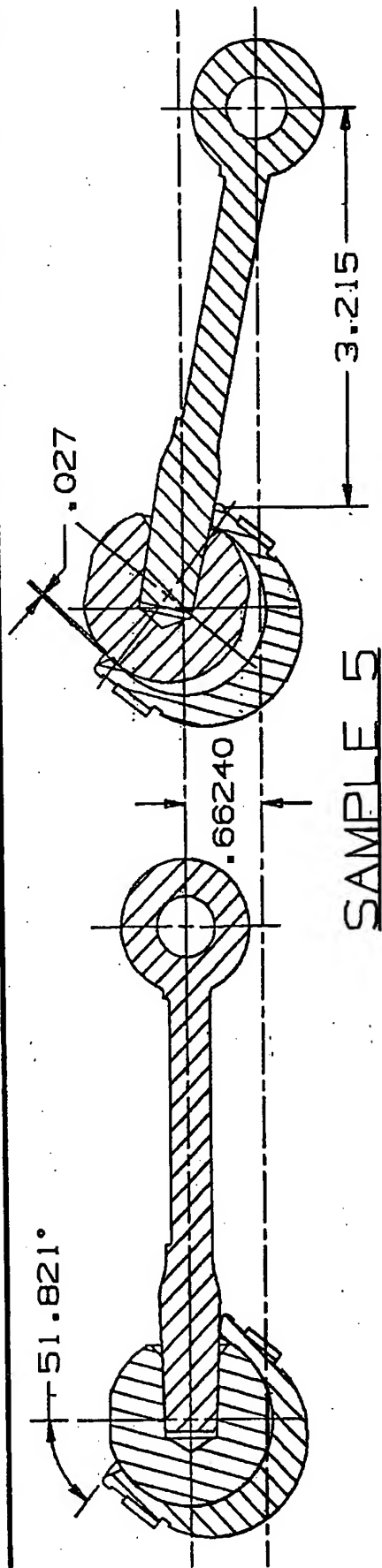
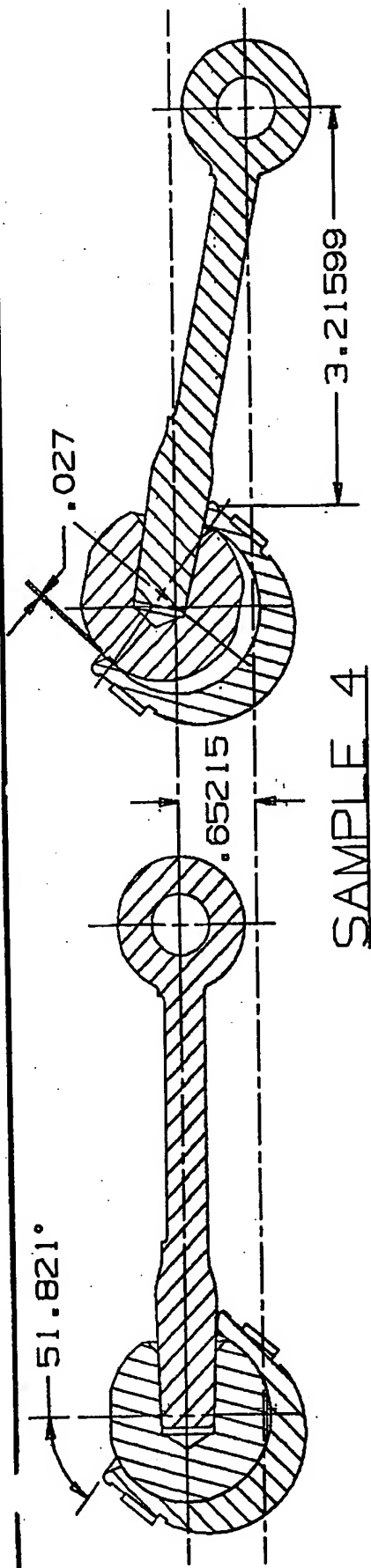
— 36/34.5 (Sample 1 Ti) — 4
— 36/34.5 (Sample 2 Ti) — 5
— 36/34.5 (Sample 2 CoCr) — 13

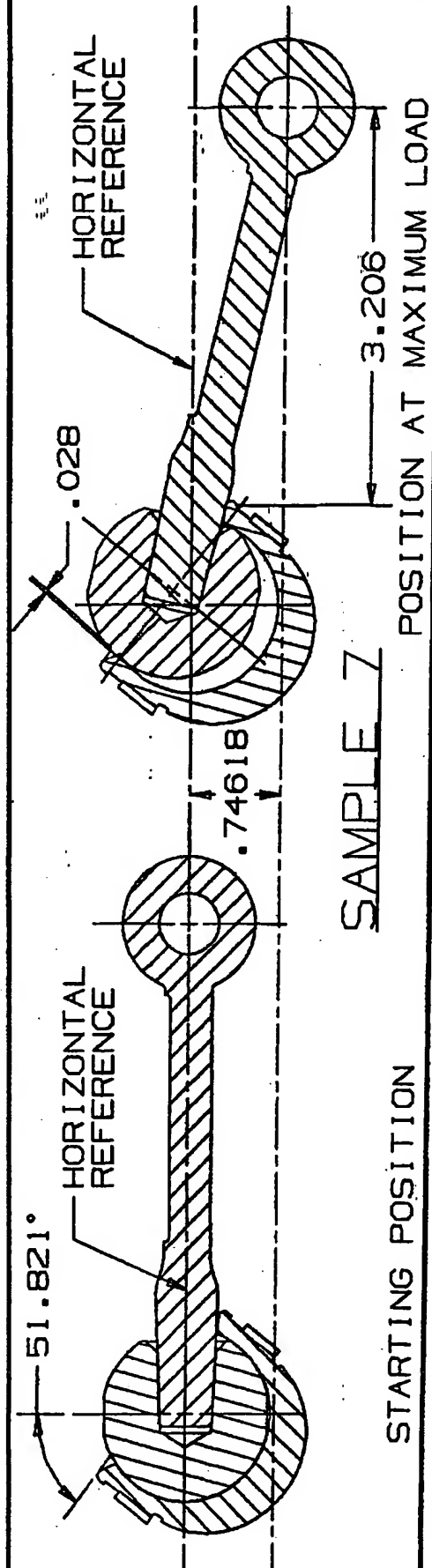
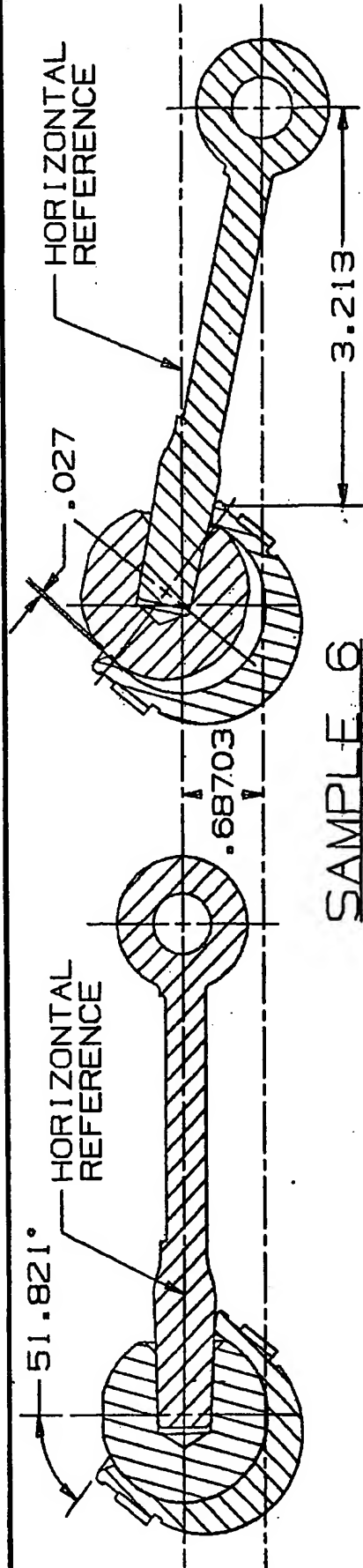
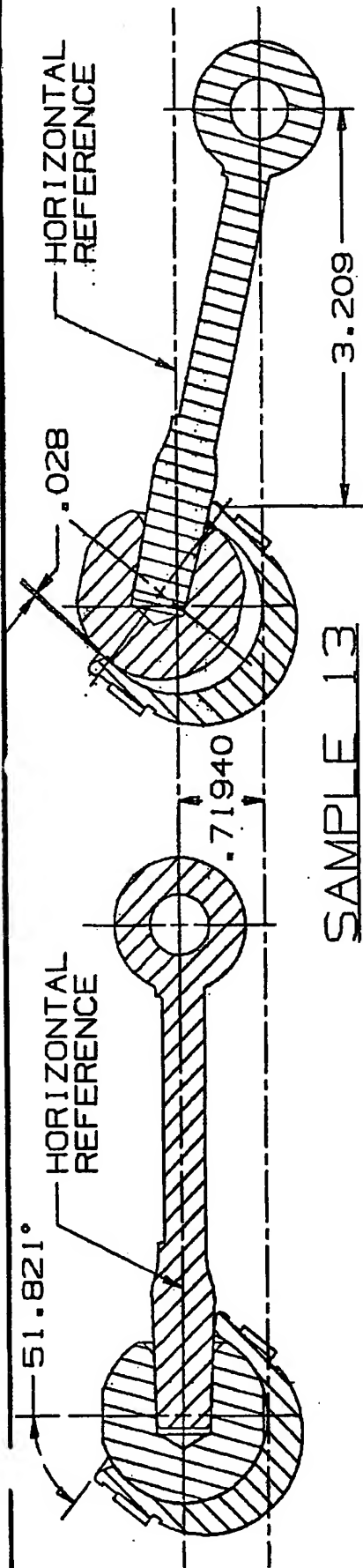
Force vs. Displacement

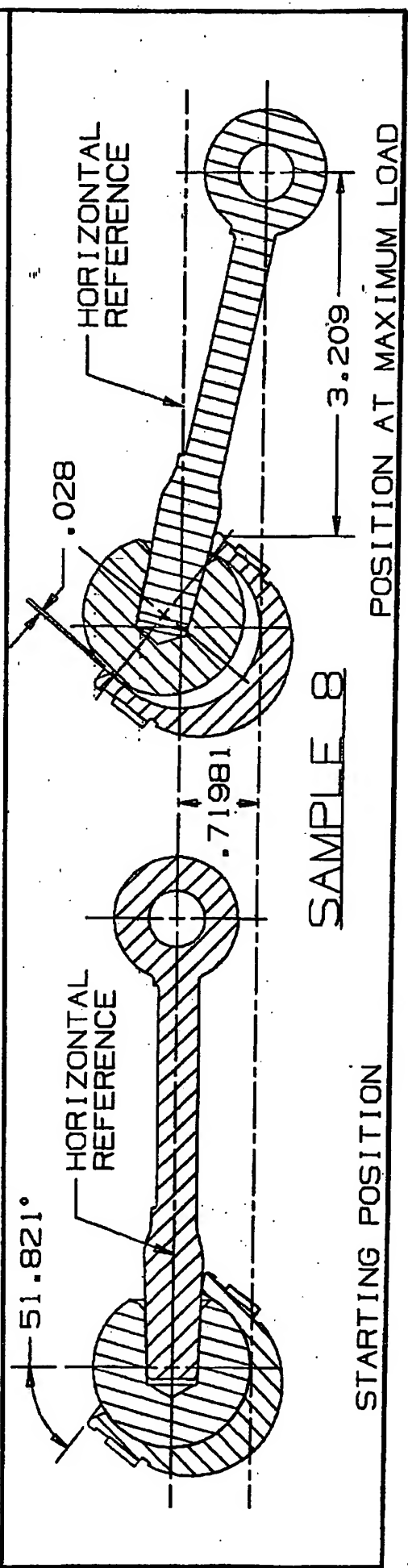
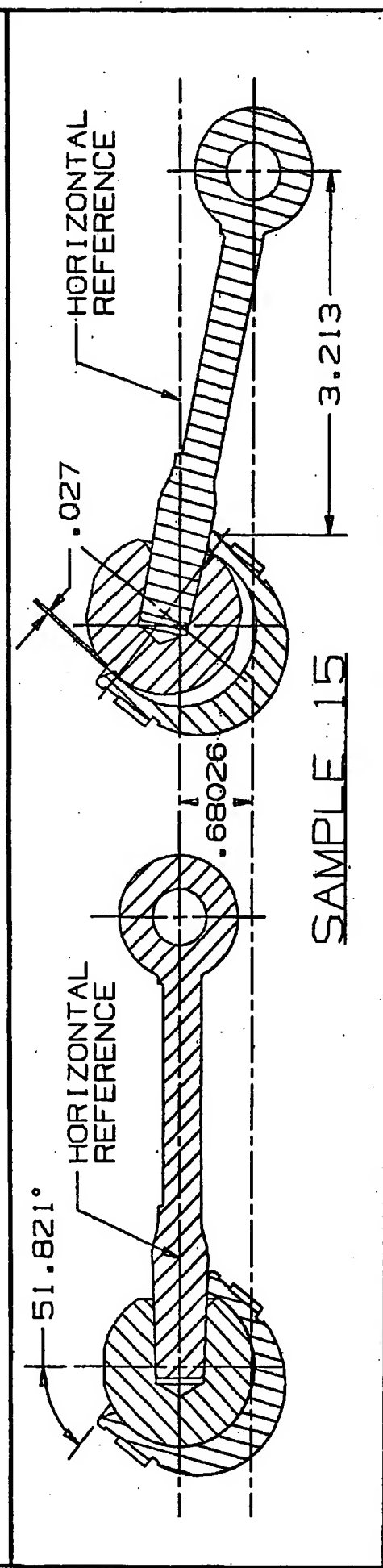
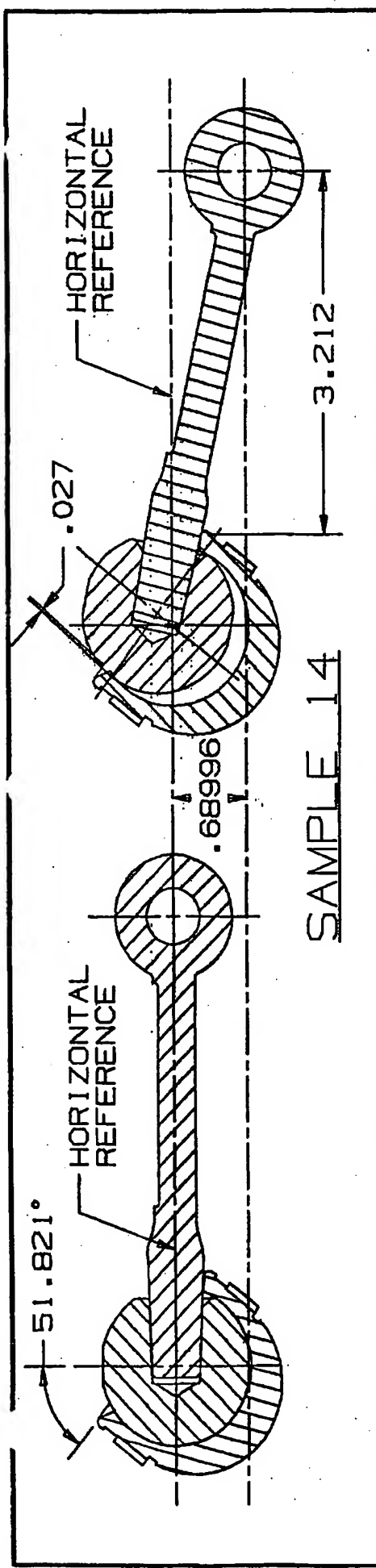


Force vs. Displacement

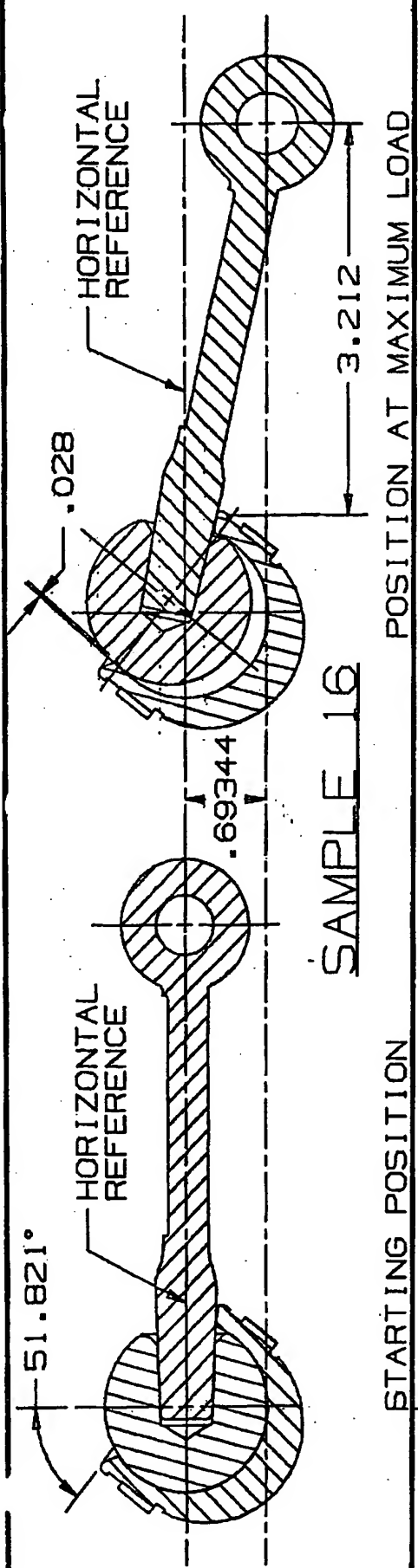












36mm Constrained Liners								
Specimen #	Initial I.D Dimension	I.D after Liq.N	Initial O.D Dimension	O.D after Liq.N	Initial O.D Ring Groove	O.D Ring Groove after Liq.N	Ring I.D	Ring Material
1	0.71722	0.71907	0.83100	0.83123	1.5770	1.5775	1.6900	Ti-6Al-4V
2	0.71775	0.71532	0.82629	0.82687	1.5730	1.5725	1.6890	Ti-6Al-4V
3	0.71743	0.71566	0.82311	0.82332	1.5700	1.5715	1.6890	Ti-6Al-4V
4	0.71764	0.71548	0.82649	0.82677	1.5730	1.5730	1.6895	Ti-6Al-4V
5	0.71616	0.71731	0.82677	0.82779	1.5740	1.5750	1.6890	Ti-6Al-4V
6	0.71789	0.71442	0.82350	0.82361	1.5710	1.5695	1.6895	Ti-6Al-4V
7	0.71639	0.71787	0.82588	0.82701	1.5720	1.5730	1.6890	Ti-6Al-4V
8	0.71789	0.71590	0.82631	0.82686	1.5720	1.5725	1.6890	Ti-6Al-4V
9	0.71708	0.71638	0.82585	0.82624	1.5720	1.5720	1.6870	Co-Cr
10	0.71763	0.71792	0.82627	0.82669	1.5730	1.5735	1.6890	Co-Cr
11	0.71781	0.71688	0.82613	0.82691	1.5730	1.5785	1.6870	Co-Cr
12	0.7163	0.71701	0.82508	0.82619	1.5750	1.5730	1.6880	Co-Cr
13	0.71714	0.69682	0.82681	0.82805	1.5750	1.5760	1.6880	Co-Cr
14	0.7159	0.71719	0.82617	0.82785	1.5730	1.5740	1.6870	Co-Cr
15	0.71638	0.71824	0.82548	0.82641	1.5720	1.5725	1.6885	Co-Cr
16	0.71708	0.71752	0.82550	0.82605	1.5750	1.5760	1.6890	Co-Cr
17	0.71765	0.71917	0.82868	0.82863	1.5750	1.5750	1.6890	Co-Cr
18	0.71688	0.71789	0.82553	0.83822	1.5750	1.5755	1.6890	Co-Cr
19	0.71807	0.71841	0.82865	0.82875	1.5730	1.5750	1.6890	Co-Cr
20	0.71748	0.71839	0.82678	0.82733	1.5720	1.5730	1.6890	Co-Cr

NOT Put in Liquid Nitrogen			
Specimen #	Difference	Difference	Difference
1	-0.0019	-0.0002	-0.0005
2	0.0024	-0.0008	0.0005
3	0.0018	-0.0002	-0.0015
4	0.0022	-0.0003	0.0000
5	-0.0011	-0.0010	-0.0010
6	0.0035	-0.0001	0.0015
7	-0.0015	-0.0011	-0.0010
8	0.0020	-0.0007	-0.0005
9	0.0007	-0.0004	0.0000
10	-0.0003	-0.0004	-0.0005
11	0.0011	0.0002	-0.0035
12	-0.0007	-0.0011	0.0020
13	0.0203	-0.0012	-0.0010
14	-0.0013	-0.0017	-0.0010
15	-0.0019	-0.0009	-0.0005
16	-0.0004	-0.0005	-0.0010
17	-0.0015	-0.0010	0.0000
18	-0.0010	-0.0127	-0.0005
19	-0.0003	-0.0001	-0.0020
20	-0.0009	-0.0008	-0.0010

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